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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,953

02/09/2004

Robert W. Brocia

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7590

04/10/2006

MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



Art Unit: 1655

Please update the continuing information in the specification. This application is a CIP, please inform the examiner as to how it differs from the parent application 08/496,806.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris.

Morris (5,173,434) entitled "Measurement of Color Reactions by Monitoring a Change of Fluorescence" teaches in column 2 last paragraph, fluorescence quenching is described for fluorogenic substrates for assaying enzymes. The synthetic substrate contains a quenching and fluorescing group which is generated. In column 4 line 24 the assay detects the concentration of substances in a colorimetric, turbidimetric or nephelometric reaction with a reader. In column 5 first full paragraph, chromogenic reagents are disclosed which have an absorption spectrum that overlaps the spectrum of a fluorophore. See the claims.

All the features of the claims are taught by Morris for the same function as claimed.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a single analyte, glucose, does not reasonably provide enablement for any analyte, light emitting moiety, or light absorbing moiety. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 1 the terms "an analyte", "a light emitting moiety", and "light absorbing moiety" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such substance would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for a single specific analyte and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.

Art Unit: 1655

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The claims must be carefully rewritten in accordance with standard US patent practice. There are many instances of lack of antecedent basis in the claims, for example i claim 1 line 1, "the concentration", in claim 4, "the substrate", "the product", "the conversion", claim 6 "the reagents". In claim 1 "if needed" is unclear as to when it would be needed. Claim 1 is an incomplete method claim where standard method steps may include contacting, determining, correlating. Claim 7 is in improper Jepsen format. And claim 7 is not understood as to what the mixture may be or how the fluorescence is dimunited.

The disclosure is objected to because of the following informalities:

The specification is objected to because it does not contain the standard headings and sections. Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Brocia (US 2005/0233401 A1) teaches an assay.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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